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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July, 2, 1996

MEMORANDUM

SUBJECT: Terbufos: American Cyanamid RED rebuttal Package; DP Barcode 225034

FROM: Mark Dow, Ph. D., Section Head
Registration Section III
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

and

Francis Suhre, Acting Section Head
Special Review and Registration Section
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

TO: William Hazel, Ph. D., Section Head
Special Review Section
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

In response to the Draft Terbufos RED Chapter (HED revised chapter dated 10/17/95) American Cyanamid submitted a rebuttal package. Documents forwarded to OREB for review were a transmittal letter and reports entitled: COUNTER® Systemic Insecticide Nematicide Overview of Potential Human Exposure; Worker Exposure from Handling Granular Insecticides; COUNTER CR and COUNTER 15 G Dust Generation and Characterization; and Response to the US EPA Regarding Acute Dietary and Worker Exposure Concerns Raised in the Preliminary Science Assessment for the Reregistration of Terbufos.

A preliminary review of these documents indicated no significant revision to the occupational and residential exposure assessment was warranted. RCAB was informed of these findings in a

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meeting on 5/30/96. A more detailed response to Cyanamid's rebuttal is presented below; Part one describes OREB policies (prepared by M. Dow) relevant to Cyanamid's rebuttal and part two addresses the specific exposure assumptions challenged by Cyanamid and provides OREB's comments and conclusions (prepared by F. Suhre) with respect to Cyanamid's rebuttal.

I.) OREB Policies Relevant to Assessing Cyanamid's Rebuttal

1.) Pro-rating exposure by weighted or relative amounts of various formulations used/marketed. It is commonly accepted by students of occupational pesticide exposure, and is correlated by data in PHED, that the amount of exposure is based on "amount handled" (e.g., loaded or applied, etc...). That of course is modified by various loading or delivery systems. Therefore, it is the amount per unit (acre usually) and the total number of units that affects exposure, not whether the active ingredient is from a 10% versus a 50% formulation. So, the calculated Average Daily Dose is dependant upon total amount of active handled per job function.

2.) Rates of application. It is policy to assess acute effects based upon the highest labelled rates of application combined with commonly accepted application/use practices and an average work day/cycle. This would apply to short term or intermediate term exposures. For cancer or chronic toxic effects, the policy is to assess exposure based on "average" rates of application.

3.) PHED subsetting. The Agency PHED subsets are very carefully constructed to account for current label directions regarding clothing, PPE and application/use practices. Unless there are errors of fact in terms of OREB's interpretation of any of these factors, the Agency subsets will be utilized.

4.) Apron protection factor. OREB acknowledges that there is an amount of protection afforded from the use of a chemical resistant or water proof apron. PHED has NO study data with which to assess the amount of protection (usually only to a pesticide loader). In a 1990 paper by Thongsinthusak et al., (Calif. Dep. Pestic. Regulation), a range of protection to the covered areas was presented. The range was 78-99% protection. This excluded only 48% protection from exposure to ethazol. So, OREB concedes that proper use of an apron will probably help protect from "catastrophic" exposure i.e., spills, splashes etc but that such use will probably not significantly affect the estimates of exposure in the OREB RED chapter.

5.) Extrapolating from exposure to liquids (sprays) to exposure to solids (granulars). It is commonly accepted that with common delivery or loading systems, exposure to liquids is basically equivocal. However, exposure to dry systems is markedly different. Physical characteristics in that sense do impact upon the amount of exposure. Therefore, OREB does not

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accept the notion that one extrapolates from open v. closed cab data for liquids to open v. closed situations for granules.

6.) Acres treated. For most field crops, in conjunction with registrants, grower groups etc, it has been commonly accepted that for ground application, about 100 acres/per day are treated. For fixed wing aerial, about 350 acres per day is the default. Obviously for crops such as cranberries, ginseng and many specialty crops, the acreages are adjusted just as they would be for forestry sprays or aerial mosquito adulticides etc.

7.) The issue of inhaled v. respirable particles was referred to the toxicology/pharmacokinetic people. Their conclusion in this case was that both "levels" of exposure contributed to the total respiratory exposure and therefore the PHED estimates of respiratory exposure are utilized.

8.) Engineering controls. Protection factors for "Lock n' Load" are already included in PHEDs estimates of exposure.

II.) **Exposure Assumptions Challenged by Cyanamid followed by OREB's Comments and Conclusions**

1.) **Cyanamid's rebuttal:** OREB assumed the maximum labelled rate in calculating daily exposure. Cyanamid recommends use of a weighted average for sugar beets and grain sorghum (see below).

OREB Comment: The HED Draft Terbufos RED Chapter (revised 10/17/95) calculates daily exposure using maximum labelled rates for sugar beets (4.35 lbs ai/A), grain sorghum (3.92 lbs ai/A), and corn (1.97 lbs. ai/A) and the typical rate for corn (1.12 lbs ai/A) (see below). OREB's policy is to assess acute effects based upon the highest labelled rates of application combined with commonly accepted application/use practices and an average work day/cycle. This would apply to short term and intermediate term exposures. For cancer or chronic toxic effects, the policy is to assess exposure based on "average" rates of application..

OREB Conclusion: The Agency Terbufos Draft RED Chapter should not be revised to consider a weighted application rates for sugar beets and grain sorghum.

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	Rate lbs. ai/A	
	OREB	Cyanamid
Sugar beets	4.35 (max)	1.43 (weighted)
Sorghum	3.92 (max)	1.1 (weighted)
Corn	1.97 (max)	not provided
Corn	1.12 (typical).	not provided

2.) **Cyanamid rebuttal:** OREB should consider the additional protection afforded by an apron (90% reduction to chest and thighs) since the product label requires use of an apron.

OREB Comment: For REDs, OREB generally calculates daily dermal exposure assuming personal protective equipment (PPE) stipulated by the WPS. For TOX Category I pesticides WPS requires ls/lp/coveralls/gloves. PHED has no data with which to assess the amount of protection (usually only to a pesticide loader) afforded by an apron. OREB acknowledges that an apron would reduce dermal exposure to thighs and chest particularly in cases involving accidental spills and splashes. To estimate mitigation afforded by an apron OREB assumed a 90% reduction to the covered area (thighs and chest) . Adjusting the PHED unit exposure for chest and thights the total dermal exposure decreases from 0.0031 to 0.0025 mg/lb ai handled (see below).

OREB Conclusion: The Agency Terbufos Draft RED Chapter should not be revised to reflect exposure mitigation from additional protection afforded by an apron. OREB acknowledges that proper use of an apron will help protect from "catastrophic" exposure i.e., spills, and splashes but that such use will not significantly affect the total dermal exposure estimates in the OREB RED chapter which is based on PPE's required by the WPS for a Category I Pesticide. .

Total dermal exposure (mg/lb ai) with and without an apron and ls/lp/coveralls/gloves

	Without Apron	With Apron
sugar beets	0.0031	0.0025
Sorghum	0.0031	0.0025
Corn	0.0031	0.0025

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3.) **Cyanamid rebuttal:** the 50x conversion factor used by OREB to back calculate applicator exposure from open cab application of a granular formulation is overly conservative. Cyanamid recommends use of a 10x conversion factor to estimate open cab exposure from closed cab data (see below). Cyanamid provided a comparison of PHED data for open and closed cab application of liquid formulations to support their recommendation.

OREB Comment: dermal exposure from application of granular and liquid formulations is significantly different.

OREB Conclusion: The Agency Terbufos Draft RED Chapter should not be revised to reflect the lower exposure estimate suggested by Cyanamid for open cab application. OREB does not agree with Cyanamid's extrapolation from open v. closed cab data for liquids to open v. closed cab data for granules.

Conversion factor from closed to open cab

EPA (50x)	Cyanamid (10x)

4.) **Cyanamid rebuttal:** inhalation exposure assessments for terbufos should not be included as part of the overall occupational risk assessment because formulated products reflect negligible health risk via the respiratory route of exposure. Particle size distribution data were provided to demonstrate that the CR formulation produces 0.2% dust and that 50% of the dust could be inhaled and 23% respired.; and that the G formulation produces 3.4% dust and that 60% of the dust could be inhaled and 40% respirated.

OREB Comment: An HED toxicologist (John Whalan) concluded that all dust particles are assumed to result in inhalation exposure and that inhalation risk assessments are required for COUNTER CR and COUNTER 15 G. (W.Hazel memo dated 6/6/96)

OREB Conclusion: Cyanamid's request to exclude the inhalation exposure assessments for COUNTER CR and COUNTER 15 G from the Terbufos RED Chapter is denied.

cc: Amyl Farrell (SRRD)
Chemical File

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